

VETERINARY BIOLOGICS

PROGRAM PROFILE

Goal	Prevent worthless, contaminated, dangerous, or harmful veterinary biologics from reaching consumers.
Enabling Legislation	21 USC 151-158 Virus-Serum-Toxin Act of March 14, 1913, and the Food Security Act amended December 23, 1985. Program began in 1924.
Economic Significance	APHIS protects the multi-billion dollar U.S. pet and livestock industries by preventing the production, distribution, and importation of worthless, contaminated, or harmful products. APHIS does this by regulating highly competitive industries that make use of rapid growth in microbiological techniques to develop a new array of sophisticated products. APHIS has the task of ensuring product safety and effectiveness without hindering development of beneficial products for American agriculture.
Principal approach and methods Used to Achieve Goals	Regulatory program that consists of licensing all products, inspecting licensed facilities, and testing samples of licensed products. Program requires veterinary biologics producers to be Federally licensed and meet Federal standards. Importation of veterinary biological products is regulated through issuance of permits. Supports APHIS program by ensuring that genetically engineered veterinary biologics are fully tested and comply with the National Environmental Policy Act prior to being released into environment. The Field Office at Ames, Iowa, conducts inspections of licensed establishments and products, and monitors product performance. The National Veterinary Services Laboratories (NVSL) conduct prelicense and check testing, develop new standard requirement tests, and provide references and reagents for standard requirement testing.
History	The program began in 1913. In 1945, veterinary biologics underwent a major change with development of live and modified live-virus vaccines. As a result, more vaccines and fewer serums and bacterium were produced. In 1985, the first license for a genetically engineered product, a

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pseudorabies vaccine, was issued. In 1986, APHIS received authority to regulate producers who distribute veterinary biologics in intrastate commerce. APHIS regulations governing intrastate commerce in veterinary biologics are now in effect. Since 1986, APHIS has licensed other recombinant DNA techniques that help us detect diseases like Johnne's disease and chicken anemia.

State and Local Cooperation

None

Involvement of Other Agencies

Justice Department (prosecute violations); FDA (regulates medicines, drugs, and chemicals used to treat or cure animal diseases); NIH (public health aspects of veterinary biologics); and Customs Service (seizure of illegal imports).

RESOURCE DATA

-----Obligations-----

	<u>Direct</u>	<u>Reimbursement</u>	<u>User Fees</u>	<u>Staff-Years</u>
FY 1997	10,400,356	--	--	166
FY 1998	10,203,454	--	--	165
FY 1999	10,124,339	--	--	165
FY 2000 (est.)	10,337,000	--	--	155
FY 2001 (est.)	10,751,000	--	--	154

	<u>APHIS</u>	<u>Coop</u>	<u>Total</u>	<u>CCC</u>	<u>Contingency Fund</u>
Cum.	\$234,914,622	--	\$234,914,622	--	--

RECENT ACCOMPLISHMENTS

Licenses

In FY 1999, APHIS issued 139 product licenses. Veterinarians and animal owners now have 34 new products for the diagnosis, prevention, or treatment of animal diseases. The Agency also terminated 56 product licenses at licensee request for products no longer produced, as compared to 60 in FY 1998 and 102 in FY 1997.

There were 2,529 active licensed or permitted products in FY 1999.

Serials Tested

APHIS approved 16,644 serials of veterinary biologics in FY 1999, while rejecting 19 serials for failing to meet Agency requirements. The Agency conducted 3,237 tests on 1,517 of the 11,809 serials eligible for testing.

Regulatory Actions

APHIS performed 13 regulatory actions and 5 investigations of possible regulation violations in FY 1999.

Reagents

APHIS shipped 5,142 vials of reagents to facilitate testing consistency and quality biologics manufacturers and other regulatory authorities. In addition, APHIS developed 20 new tests and reagents.

Certificates Issued

APHIS issued over 1,721 official certificates that indicate licensed production and testing facilities and products have met or exceeded marketing requirements. The regulated industry used these certificates to register their products for sale in foreign countries. The confidence that foreign regulators have in the U.S. veterinary biologics licensing, testing, and inspection system is reflected in their readiness to accept our products. Center for Veterinary Biologics (CVB) officials provided informational presentations at international conferences to bolster foreign regulators' confidence.

International Trade

The veterinary biologics program continued efforts to reduce trade barriers that limit the sale of veterinary biological products overseas. Program officials continued discussions with representatives of the European and U.S. biologics industries and with regulatory officials from the European Union (EU) regarding a Mutual Recognition Agreement (MRA) concerning the marketing of veterinary biologics.

Interaction with Canadian regulatory officials continued under the Canada-United States Trade Agreement and the North American Free Trade Agreement. Canadian regulatory officials and CVB personnel conducted joint inspections at facilities in Australia, Canada, Mexico, and New Zealand. We held meetings with regulatory officials

from Asia, Australia, the European Union, Germany, Japan, and Russia, to facilitate exchange of information and encourage discussion of regulatory issues.

In March 1999, the 5th Steering Committee Meeting of the Veterinary International Cooperation on Harmonization was held to review the progress of four working groups addressing projects concerning the harmonization of quality test requirements and post licensing monitoring procedures (pharmacovigilance) for veterinary biological products. Two of the working groups developed proposed harmonized guidelines for Stability and Good Clinical Practices and released them for industry comment in 1999. The other two working groups have prepared discussion material on pharmacovigilance and quality. The Committee expects to discuss this material at the next scheduled meeting in 2000.

Testing of Master Seeds

In FY 1999, APHIS tested 6 genetically engineered master seeds. These included bacterial gene-deleted agents and viral-vectored vaccines. A new technology (real-time quantitative polymerase chain reaction) was researched, instrumentation was purchased, and initial training was performed. The program developed draft requirements for naked DNA vaccines and discussed them with the biologics industry. The program discussed requirements for transgenic plant-based biologics and scheduled a one-day transgenic plant workshop and Public Hearing.

Public Meeting

The Agency held a special topic Veterinary Biologics Public Meeting on the regulation of antibody products to maintain communications with the public, customers, and stakeholders. The purpose of this meeting was to acquire additional information from industry, veterinary practitioners, and other parties interested in the current regulations. The program is reviewing and evaluating comments and statements from the meeting. A response plan is under internal review. We will soon publish a Proposed Rule addressing antibody products.